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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,812	02/04/2002	Richard J. Greff	29985/05-117A	8436

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/068,812	GREFF, RICHARD J.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) *39-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's request for RCE and amendment, both filed 10/10/2006.

Claims 1-21 have been canceled, and claims 22-41 have been added.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 22-38, drawn to composition comprising gelatin and wetting agent and method of its use, classified in class 424, subclass 443.

   II. Claims 39-41, drawn to kit comprising syringe and non-hydrated pledget, classified in class 604, subclass 181.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and consequently different modes of

operation because Group II require a syringe and non-hydrated pledget that are not required by group I.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Mr. Brent Matthias on December 14, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 22-38. Affirmation of this election must be made by applicant in replying to this

Office action. Claims 39-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 22-38 are included in the prosecution.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 22-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection because nowhere in the specification applicants have disclosed the wetting agent "facilitates spreading and penetration of an aqueous solution into the gelatin sponge thereby

decreasing a hydration time of the gelatin sponge" as instantly claimed by claims 22 and 34. Additionally, claim 34 include new matter that is the steps of "providing an aqueous solution" and the step of "contacting the gelatin composition with the aqueous solution". Claim 24 further recites "anionic surfactant" that is not described any where in the specification as originally filed. Furthermore, claims 27 and 37 recite "the gelatin composition comprises from about 0.01 to about 5 wt % of the wetting agent" and nowhere applicants have disclosed that amount of the wetting agent. On page 9, lines 20-27 applicants disclosed: "the gelatin composition comprises from about 0.01 to 10 wt % of the wetting agent". On last line of the page 9 and lines 1-2 of page 10 applicants disclosed that the gelatin composition comprises from about 0.01 to about wt 5% of the wetting agent after evaporation of the liquid solvent.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 25 and 34-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 25, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite because it is subject of more than one interpretation, and one interpretation would render the claim

unpatentable over the prior art. In the present instance, the broad limitation is "polyoxyalkylenes" and narrower limitations are "ester capped polyoxyalkylenes" and "ether capped polyoxyalkylenes".

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relation of the steps of "providing an aqueous solution" and "contacting the gelatin composition with the aqueous solution" to the method for decreasing the hydration time of the gelatin composition.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 22-29, 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 02-182259 (259).

JP '259 teaches composition comprising crosslinked gelatin, and solution comprising surfactant impregnated into the crosslinked gelatin (see the provided abstract). The composition comprises 1-50 % of gelatin in aqueous solution and from 0.1 % to 30 % of the aqueous solution is the surfactant (page 5, last paragraph; page 6, first full paragraph). The reference disclosed in the process of making the composition, the gelatin solution is prepared, then, the surfactant is added followed by foaming and drying, i.e. evaporation of the solvent (page 6, second full paragraph; page 10, operational example 1). The composition easily dissolves in blood or body fluids, i.e. bioabsorbable (page 7, third line). The surfactants disclosed by the reference include sodium lauric sulfuric acid, polyethylene glycol alkyl ether and sorbitan fatty acid ester (page 7, second full paragraph). The material disclosed by the reference that comprises cross-linked gelatin and the same wetting agent, is expected to decrease the hydration time of the cross-linked gelatin that claimed in claims 22 and 34. Furthermore, on page 5, lines 25-27 of the present disclosure, applicants disclosed that the hydration time is the time needed to prepare the gelatin for use, and the reference disclosed on page 11, third full paragraph that hemostatic composition showed slight swelling and arrested bleeding in 60 seconds, i.e. the composition was ready for use.

The difference between JP '259 and the present invention is that JP '259 does not teach coating of the wetting agent on the surface of the cross-linked gelatin. However, the reference disclosed soaking of gelatin sponge in the cross-linking solution, i.e. wetting agent. After drying the mixture of gelatin and the wetting agent of the reference, it is expected to have some wetting agents on the surface of the product, which reads on coating. In any event, the presence of the wetting agent as a coating on the surface does not impart patentability of the claims, absent evidence to the contrary. No superior and unexpected results of record obtained by coating the wetting agent on the surface of the gelatin versus incorporating the wetting agent into the gelatin.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising cross-linked gelatin sponge soaked in wetting agent as disclosed by JP '259, and it is expected to have the wetting agent on the surface of the product after drying as a coating.

15. Claims 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of US 6,603,061 ('061).

The teachings of JP '259 are discussed above. However, JP '259 does not teach that the composition is sterilized and packaged as claimed by claim 30, or the composition comprising thrombus enhancing agent as claimed in claim 32, or antimicrobial agent as claimed in claim 33.

US '061 teaches a biocompatible hemostatic composition comprising non-hydrated cross-linked gelatin, plasticizer and hydrating agent (col.3, lines 4-6, 43, 67;

col.4, lines 11-12, 41-42; col.5, line 40; col.8). The composition further comprises active agent such as antibiotics and hemostatic agents including thrombin and clotting factors (col.11, lines 16-35). The composition can be in the form of sterile package (col.3, lines 33-34; col.5, lines 6-10, 25-35; col.8, lines 32-36).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide the hemostatic composition disclosed by JP '259 and add antimicrobial and/or clotting factors as disclosed by US '061, motivated by the teaching of US '061 that such agents are beneficial for hemostasis, with reasonable expectation of having hemostatic composition comprises cross-linked gelatin and wetting agent and further comprises antimicrobial and/or clotting factors that are beneficial for hemostasis. Additionally, one having ordinary skill in the art would have been motivated to sterilize and package the gelatin sponge produced by JP '259 as disclosed by US '061, motivated by the logic of the wound dressing art that sterilization and package of gelatin material will be safer to use on the wound or bleeding site, with reasonable expectation of having sterile packaged gelatin sponge incorporating wetting agent that is safe to apply to bleeding site or wound.

16. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP '259 in view of EP 5568 334 ('334).

The teachings of JP '259 are discussed above. However, JP '259 does not teach that the composition comprising growth factor as instantly claimed claim 31.

EP '334 teaches collagen containing sponge comprising cross linked gelatin and active agent, preferably growth factors which enhanced wound healing and nerve regeneration (abstract; col.5, lines 22-30).

Therefore, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide hemostatic composition comprising cross linked gelatin and wetting agent as disclosed by JP '259, and add growth factors to the composition as disclosed by EP '334, motivated by the teaching of US '334 that growth factors are preferred active ingredient to be added to hemostatic gelatin wound treating composition because growth factors enhance wound healing and nerve regeneration, with reasonable expectation of having composition comprising cross linked gelatin, wetting agent and growth factors wherein the composition enhances wound healing and nerve regeneration successfully.

Response to Arguments

17. Applicant's arguments with respect to claims 22-38 have been considered but are moot in view of the new ground(s) of rejection.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,595,735 disclosed hemostatic composition comprising polyethylene glycol adsorbed on gelatin sponge; col.2, lines 35-66. US 4,920,158 disclosed hemostatic composition comprising crosslinked gelatin (GELFOAM) and glycerin, example 1.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
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Art Unit 1615

Isis Ghali